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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,914	09/14/2006	Michael Farrell	3869/041 US	2011
22440 7590 09/16/2009 GOTTLIEB RACKMAN & REISMAN PC 270 MADISON AVENUE 8TH FLOOR NEW YORK, NY 10016-0601			EXAMINER DOUGLAS, STEVEN O	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 09/16/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,914	FARRELL ET AL.	
	Examiner	Art Unit	
	/Steven O. Douglas/	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) 17-19, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09022009</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US PGPub 2004/0111040).

Regarding Claim 1, Ni discloses method for monitoring the cardiovascular condition of a patient while treating sleep disordered breathing. Ni discloses delivering positive airway pressure at therapeutic levels for treatment of sleep disordered breathing (para. 0050, lines 10-14). Ni also discloses detecting and recording events associated with the treatment of the patient's sleep disordered breathing (para. 0052, lines 1-8).

Ni also discloses storing information concerning the cardiovascular condition of the patient (para. 0056, lines 10-17).

Ni also discloses relating to each other the stored information concerning the cardiovascular condition of the patient and the recorded events associated with the treatment of the patient's sleep disordered breathing (para. 0053 line 1-10 describes how signals associated with sleep disordered breathing such as heart rate are overlapped to detect disordered breathing).

Regarding Claim 2, Ni discloses recording and detecting apneas and hypopneas (para. 0054, line 4).

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Regarding Claims 3 and 4, the information on the cardiovascular condition of the patient is stored (para. 0056, lines 10-15) and related to recorded sleep disordered breathing events over time (overlapping signals are used to detect sleep disordered breathing, see para. 0053, lines 1-5).

Regarding Claim 5, Ni discloses a method for treating respiratory disorders and simultaneously monitoring a patient for indications of cardiovascular disease. This method includes delivering positive airway pressure at therapeutic levels for treatment of sleep disordered breathing (para. 0050, lines 10-14).

Ni also discloses detecting and recording, as a function of time (an overlapping set of signals is used, see para. 0053, lines 1-5) events associated with the treatment of the patient's sleep disordered breathing (heart rate, respiration rate, etc. in para. 0052, lines 1-8).

Ni also discloses storing as a function of time the information concerning the cardiovascular condition of the patient (the historical data stored in memory, see para. 0056, lines 10-17).

Ni also discloses relating to each other the information concerning the cardiovascular condition of the patient and the recorded events associated with the treatment of the patient's respiratory disorders (para. 0053, lines 1-5, the information on the cardiovascular condition is stored with an overlapping set of signals associated with disordered breathing to detect disordered breathing).

Regarding Claim 6, Ni discloses recording and detecting apneas and hypopneas (para. 0054, line 4).

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Regarding Claims 7 and 8, the information on the cardiovascular condition of the patient is stored (para. 0056, lines 10-15) and related to recorded sleep disordered breathing events over time (para. 0053, lines 1-5).

Regarding Claims 9, 10, and 11, Ni discloses monitoring hear rate (para. 0052, line 2) continuously together with sleep disordered breathing information on similar time scales (the overlapping signals, para. 0053, lines 1-5). Ni also discloses observing changes in the patient's heart rate associated with changes in sleep disordered breathing to relate to each other the cardiovascular and sleep disordered breathing conditions of the patient (para. 0053, lines 1-5, sleep related signals such as heart rate are used to detect disordered breathing).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al. (US PGPub 2004/0111040).

Regarding Claim 12, Ni discloses performing long-term monitoring of the condition of a patient while treating the patient's sleep disordered breathing (para. 0056, lines 15-17, the memory circuitry stores historical data and detect disordered breathing over time, which appears to be long term monitoring).

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Ni also discloses collecting and storing data concerning the condition of the patient that is obtained from the long term monitoring (the sleep disordered breathing data is stored, see para. 0056, lines 5-10).

Ni does not disclose, in the embodiment shown in Fig. 1 and previously referred to, making the stored data available to a clinician who is treating at least one disease of the patient other than sleep disordered breathing. Ni discloses in another embodiment, shown in Figure 3, making the stored data available to a physician treating at least one disease of the patient other than sleep disordered breathing via a wireless programmer unit 380 (para. 0076, lines 10-20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add a programmer unit as taught by the second embodiment of Ni to the first embodiment of Ni so that a user can wirelessly access data and control the patient's treatment with ease from a remote location.

Regarding Claim 13, the data is collected and stored while delivering positive airway pressure to the patient at therapeutic levels (para. 0050, lines 10-14).

Regarding Claims 14-16, the data that is stored and made available concerns the cardiovascular condition of the patient (heart rate, para. 0052, lines 1-8) and events associated with the treatment of the patient's sleep disordered breathing (any of the other events in para. 0052).

Response to Arguments

Applicant's arguments filed 6/4/09 have been fully considered but they are not persuasive. Firstly, in regard to Applicant's repeated argument that Ni has an opposite purpose

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than that defined by the instant claims (i.e. Ni records cardiovascular information in order to diagnose sleep disordered breathing), Examiner disagrees. Examiner takes the position that the cardiovascular information recorded by Ni is certainly is related to sleep disordered breathing information and Ni's diagnosis of sleep disordered breathing as, for example, sleep apnea is most certainly related to a cardiovascular condition of a patient. Essentially, Examiner is taking the position that the cardiovascular condition of a patient and the recorded sleep disordered breathing information such as heart rate, etc.. are directly related or correlated with each other.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885.

The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/
Primary Examiner
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SD
9/14/09